BK040069

Trima Automated Blood Component System - Blood Component Sampling Accessory

Summary of Safety and Effectiveness

Manufacturer:	Gambro BCT, Incorporated 10811 W. Collins Avenue Lakewood, Colorado 80215
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Date of Summary Preparation:	August 2004
Trade Name of Device:	Trima Automated Blood Component Collection System - Blood Component Sampling Accessory.
Common Name:	Automated Blood Component Collection System
Classification Name:	Automated Blood Cell Separator (21 CFR 864.9245)
Predicate Devices:	Trima Automated Blood Component Collection System (510(k)'s BK970002, BK970023, BK990025, BK010006, BK010046, BK010050)

Device Description

A growing number of blood centers in North America and Europe are implementing methods to detect contaminating bacteria in platelet products as an approach to further enhance platelet safety. The purpose of this new device is to provide tubing set enhancements that facilitate the sampling process for routine bacterial testing. Two options are available:

1) Integration of a specially designed platelet sampling system into the existing Trima Platelet/Plasma/RBC sets. Offering a pre-attached sampling system adds convenience and minimizes the risk of introducing

bacteria into the process by allowing aseptic removal of a sample from the platelet bag without need for sterile docking.

2) A new dockable Accessory Blood Component Sampling Set that is identical in design as the integrated sampling system. This set can be attached to Spectra, Trima dual-stage, and competitive sets through sterile docking, and will allow customers to streamline their sampling process across blood component collection technologies.

Intended Use:

The sampling system allows aseptic removal of a sample from the platelet bag for subsequent testing. The sampling system does not contact blood or fluids that are reinfused to a donor or patient.

Technological Comparison:

No new material formulations are used in the Blood Component Sampling Accessory other than those used in current versions of Trima disposable tubing sets. The Trima System disposable tubing sets with the integrated blood component sampling accessory or the stand-alone dockable accessory will be sterilized using the same ethylene oxide sterilization cycle currently used for Trima disposable tubing sets.

Conclusion

The Trima System Blood Component Sampling Accessory is compatible with standard blood center practices for platelet collection and post-collection handling, including transportation and storage of the product bags on platelet agitators/incubator shelves, while maintaining a closed system during handling. This new device provides enhancements that facilitate the process for routine platelet unit sampling.